

34. Withdrawal of this rejection is therefore respectfully requested.

The Official Action rejected claims 13-17, 21, and former claims 22, 24, and 27 under §112, second paragraph, as being indefinite. Claims 22 and 24 have been cancelled and redrafted as claim 33. Former claim 15 has been divided into claims 15 and 34. Former claim 17 has been divided into claims 17 and 35. Claim 27 has been cancelled. All of the bases for rejection which have been specifically listed in the Official Action have been remedied through amendment. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The Official Action rejected claims 13-16 under §102(b) as being anticipated by ROWE et al. ROWE et al. disclose a malaria erythrocyte membrane protein (PfEMP1) which mediates the binding of infected erythrocytes to endothelial cells and is encoated by a specific var gene.

The present invention claims a polypeptide of SEQ ID NO:1, which is not anticipated by the polypeptide in ROWE et al. The polypeptide of the present invention is also a parasite ligand for rosetting in *Plasmodium falciparum* and does not bind to the complement receptor 1 (CR1). The polypeptide of the applied reference binds to CR1 in addition to being a parasite ligand. Since the present invention is a parasite ligand but does not bind to CR1, the present invention is not anticipated by ROWE et al. Withdrawal of this rejection is therefore respectfully requested.

The Official Action rejected claims 13 and 17 under §103(a) as obvious over ROWE et al. in view of SU et al. ROWE et al. disclose a malaria erythrocyte membrane polypeptide. SU et al. disclose *P. falciparum* genes (var) that encode 200-350 kDa proteins having properties of antigenic variant adhesion molecules. However, ROWE et al. teach a PfEMP1 that also binds to CR1. This is a different polypeptide than the present invention which does not bind to CR1.

The present invention is a parasite ligand that does not bind to CR1 and is between 100-350 kDa. ROWE et al. teach a PfEMP1 that bind to CR1 and is a parasite ligand. SU et al. teach a PfEMP1 that is merely a parasite ligand within a range of 200-350 kDa. SU et al. do not describe the function of its PfEMP1 and it is probably not the same as ROWE's. There would, therefore, not have been motivation to combine the two disclosures. Furthermore, the present invention is a different PfEMP1 than ROWE and therefore there would be no motivation to create a PfEMP1 in a range of 200-350 kDa similar to the present invention. The combination does not guarantee that the PfEMP1 of the present invention could be made within a range of 200-350 kDa without impermissible hindsight. ROWE with SU teach away from the present invention by teaching a polypeptide that is both a parasite ligand and binds to CR1 within a range of 200-350 kDa, whereas the present invention teaches a polypeptide that does not bind CR1. ROWE et al. in combination with SU et al. do not, therefore, render the present invention obvious. Reconsideration and withdrawal of the rejection are respectfully requested.

The Official Action rejected claims 13 and 21-23 under §103(a) as being obvious over ROWE et al. in view of BARUCH et al. ROWE et al. teach a polypeptide PfEMP1 fusion protein but do not teach malarial medicaments. BARUCH et al. teach malarial medicaments comprising a PfEMP1 fusion protein. The Official Action contends that this combination renders the present invention obvious.

The present invention teaches a PfEMP1 polypeptide that does not bind to CR1, ICAM1 or TSP unlike ROWE et al. and BARUCH et al. BARUCH et al. teach a polypeptide that does bind ICAM1 and TSP in its production of a malarial medicament. BARUCH's medicament is different than the present invention's and ROWE et al. in combination with BARUCH et al. teach a different polypeptide malarial medicament with only some of the same characteristics. Taking the present invention as a whole and the references as a whole, the present invention is not rendered obvious by BARUCH et al. and ROWE et al.

Furthermore, the rejection of the Official Action is that it is essentially "obvious-to-try" to make a medicament of a polypeptide PfEMP1 that does not bind ICAM1, CR1 or TSP. A mere suggestion to try a particular compound for a new use is never enough to support a rejection under 35 USC §103. Instead, that suggestion to try a particular compound must be accompanied by evidence showing that the skilled artisan would have had a reasonable expectation of success in achieving the results provided by the invention at hand.



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ated for example in *In re Eli Lilly & Co.*, 14 USPQ  
2d 1741 (Fed. Cir. 1990):

An 'obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation may be done as a result of the disclosure, a disclosure itself does not contain a sufficient teaching of how to obtain the desired results, or that the claimed results would be obtained if certain directions were pursued.

See generally *In re O'Farrell*, 7 USPQ 2d 1673, 1781 (Fed. Cir. 1988).

In addition, as was pointed out in *In re Dow Chemical Co.*, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988):

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art....both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure (citations omitted).

ROWE et al. in combination with BARUCH et al. do not teach or suggest making the malarial medicament for a PfEMP1 that does not bind CR1 or ICAM1. It therefore follows that ROWE et al. and BARUCH et al. do not render the present invention as obvious. Reconsideration and withdrawal of this rejection are respectfully requested.

In light of the amendments discussed above, applicants believe that the present application is in condition for allowance and an early indication of the same is respectfully requested.

If the Examiner has any questions or requires clarification, the Examiner may contact the undersigned attorney so that this application may continue to be expeditiously advanced.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Respectfully submitted,

YOUNG & THOMPSON

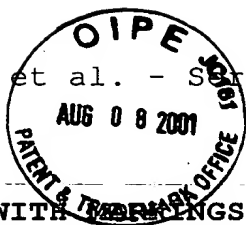
By



Andrew J. Patch  
Attorney for Applicants  
Registration No. 32,925  
745 South 23rd Street  
Arlington, VA 22202  
Telephone: 521-2297

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VERSION WITH ~~AMENDMENTS~~ TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 13 was amended as follows:

--13. (amended) An isolated polypeptide originating from a malaria erythrocyte membrane protein comprising an amino-terminal part of the sequence according to SEQ ID NO:1 [or an analogue thereof].--

Claim 14 was amended as follows:

--14. (amended) A polypeptide originating from a malaria erythrocyte membrane protein comprising at least [about] 300 amino acids of the sequence according to SEQ ID NO:1 [or a functional analogue thereof].--

Claim 15 was amended as follows:

--15. (twice amended) A polypeptide according to claim 13 comprising domain DBL-1 having about 400-500 amino acids[, preferably about 423 amino acids,] of the sequence according to SEQ ID NO:1 [or a functional analogue].

Claim 16 was amended as follows:

--16. (twice amended) A polypeptide according to claim 13 capable of essentially specific binding to a negatively charged heparan sulphate or heparan sulphate-like molecule [glycosaminoglycan-like moiety, preferably a sulfated glycosaminoglycan-like moiety].--

Claim 17 was amended as follows:

--17. (twice amended) A polypeptide according to claim 13 having a weight of about 100-300 kDa[, preferably about 280 kDa].--